Foster et al.

Application No.: 10/552,390

Filed: May 30, 2006

Page 6

REMARKS

PATENT

Atty Docket No.: MAP1130

In the present amendment, claims 1 and 10 have been amended; claims 13-26 have been canceled without prejudice or disclaimer; and claims 27-31 have been added. The amendments introduce no new matter as discussed further below, thus reconsideration of the application is respectfully requested.

Claim Amendments and New Claims

The claims have been amended to assist in clarifying the invention. All of the amendments are supported by the specification and the claims as originally filed.

In particular, claim 1 has been amended to indicate that the outer chamber of the claimed apparatus is a pressure vessel. The amendment is supported throughout the specification, for example, paragraph [0015] of the specification as published (U.S. Appl. Pub. No. 2007/0034568).

Claim 10 has been amended to recite that the baffles extend from the inner surface of the outer chamber of the apparatus. The amendment is supported throughout the specification, for example, paragraph [0066] of the specification as published.

New claim 27 has been added and recites a specific pressure range provided by the pressure vessel. New claim 27 is supported throughout the specification, for example, paragraph [0040] of the specification as published.

New claim 28 has been added and recites that the pressure vessel is an autoclave and is supported throughout the specification, for example, paragraph [0015], [0062], [0063], [0067], [0076] and [0077] of the specification as published.

New claim 29 has been added and recites a specific temperature range provided by the autoclave. The new claim is supported throughout the specification, for example, paragraph [0040] and Examples 1 and 2 of the specification as published.

Foster et al.

Application No.: 10/552,390

Filed: May 30, 2006

Page 7

New claim 30 has been added and recites a specific pressure range provided by the autoclave. New claim 30 is supported throughout the specification, for example, paragraph [0040] and Examples 1 and 2 of the specification as published.

New claim 31 has been added and incorporates the limitations of original claims 1, 5 and 6, and therefore is supported by original claims 1, 5 and 6.

PATENT

Atty Docket No.: MAP1130

No new matter is introduced by the subject amendments and the entry thereof is respectfully requested. After amendment, claims 1-12 and 26-31 will remain pending and under consideration.

Objection to the Drawings

The Office Action indicates that Figure 2 has been objected as the location of element 8 specified in Figure 2 is allegedly in direct contradiction with the claims and specification.

Additionally, the Office Action indicates that Figure 3 has been objected as elements 4 and 6 are allegedly incorrectly labeled. Without acquiescing to the reasoning presented in the Office Action, and to expedite prosecution of the instant application, Applicants submit a Replacement Sheet herewith including Figures 2 and 3 with the suggested amendments. Applicants respectfully submit that no new matter has been introduced into the Replacement Sheet and respectfully request entry of revised Figures 2 and 3 and withdrawal of the objection.

Rejections under 35 U.S.C. §102

Applicants respectfully traverse the rejection of claims 1-7, 9, 11 and 26 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,744,038 (Cham).

To anticipate, a single reference must inherently or expressly teach each and every element of claimed invention (see, *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); and MPEP § 2131).

Foster et al.

Application No.: 10/552,390

Filed: May 30, 2006

Page 8

The Office Action alleges Cham teaches each and every element of the apparatus as claimed. Without acquiescing to the reasoning presented in the Office Action, and to expedite prosecution of the instant application, Applicants have amended the claims to recite an apparatus having an "outer chamber for containing a dense gas, wherein the outer chamber is a pressure vessel". As noted in Examples 1 and 2 of the specification, the pressure vessel provides elevated pressure within the chamber and specifically to the substance contained within the inner porous chamber to facilitate dissolution or suspension of the substance in the dense gas solvent. New claim 30 has been added and recites that the pressure vessel provides between 5 and 200 bar of pressure. Cham fails to teach an apparatus wherein the outer chamber is a pressure vessel as recited in the amended claims. Further, with regard to claim 26, since Cham fails to discloses all of the claim limitations of claim 1, the reference fails to anticipate claim 26 since the claim recites a method of administering a subject a substance produced using the apparatus of claim 1.

PATENT

Atty Docket No.: MAP1130

Additional claims have also been added to further define the outer chamber as an autoclave which provides an elevated temperature and pressure. As noted in the Examples of the specification describing the synthesis of particles of ibuprofen and simvastatin, an elevated temperature and pressure is provided by the outer autoclave to facilitate synthesis of the particles. Cham fails to teach an apparatus wherein the outer chamber is an autoclave as claimed.

With regard to new claim 31, the claim recites an apparatus including the limitations of claims 5 and 6 as well as further clarifying the structure of the longitudinally extending shaft within the porous chamber. As such, the claim recites an apparatus comprising "a porous chamber within the outer chamber for containing a substance for dissolution or suspension with the solvent, the porous chamber comprising a wall allowing passage of solvent and the substance dissolved or suspended in the solvent, and a longitudinally extending shaft in fluid communication with the inlet, wherein the shaft is porous along the length of the shaft". Thus, the claim defines a shaft that includes multiple holes along the length of the shaft. Cham fails to disclose an apparatus having a shaft that is porous along its length. As noted in the Office

Foster et al.

Application No.: 10/552,390

Filed: N Page 9

Filed: May 30, 2006

Action (page 5, second paragraph), Cham discloses a shaft having an opening at the end of the shaft, as opposed to a shaft that is porous along the length of the shaft as claimed.

PATENT

Atty Docket No.: MAP1130

Applicants submit that Cham fails to anticipate the claimed invention as the reference fails to teach the each and every element of the claims. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Applicants respectfully traverse the rejection of claim 1 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 6,540,914 (Smith).

The Office Action alleges Smith teaches each and every element of the apparatus as claimed. As discussed above, without acquiescing to the reasoning presented in the Office Action, and to expedite prosecution of the instant application, Applicants have amended the claims to recite an apparatus having an "outer chamber for containing a dense gas, wherein the outer chamber is a pressure vessel". New claim 30 has been added and recites that the pressure vessel provides between 5 and 200 bar of pressure. Smith fails to teach an apparatus wherein the outer chamber is a pressure vessel as recited in the amended claims. Further, as discussed above, additional claims have also been added to define the outer chamber as an autoclave which provides an elevated temperature and pressure. Smith also fails to teach an apparatus wherein the outer chamber is an autoclave as claimed.

Applicants submit that Smith fails to anticipate the claimed invention as the reference fails to teach the each and every element of the claims. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Applicants respectfully traverse the rejection of claims 1 and 8 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 6,531,056 (Hammonds).

The Office Action alleges Hammonds teaches each and every element of the apparatus as claimed. As discussed above, without acquiescing to the reasoning presented in the Office Action, and to expedite prosecution of the instant application, Applicants have amended the

Foster et al.

Application No.: 10/552,390

Filed: May 30, 2006

Page 10

claims to recite an apparatus having an "outer chamber for containing a dense gas, wherein the outer chamber is a pressure vessel". New claim 30 has been added and recites that the pressure vessel provides between 5 and 200 bar of pressure. Hammonds fails to teach an apparatus wherein the outer chamber is a pressure vessel as recited in the amended claims. Further, as discussed above, additional claims have also been added to define the outer chamber as an autoclave which provides an elevated temperature and pressure. Hammonds also fails to teach an apparatus wherein the outer chamber is an autoclave as claimed.

PATENT

Atty Docket No.: MAP1130

Applicants submit that Hammonds fails to anticipate the claimed invention as the reference fails to teach the each and every element of the claims. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Applicants respectfully traverse the rejection of claims 1-7 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 4,957,708 (Dutton et al.; hereinafter "Dutton").

The Office Action alleges Dutton teaches each and every element of the apparatus as claimed. As discussed above, without acquiescing to the reasoning presented in the Office Action, and to expedite prosecution of the instant application, Applicants have amended the claims to recite an apparatus having an "outer chamber for containing a dense gas, wherein the outer chamber is a pressure vessel". New claim 30 has been added and recites that the pressure vessel provides between 5 and 200 bar of pressure. Dutton fails to teach an apparatus wherein the outer chamber is a pressure vessel as recited in the amended claims. Further, as discussed above, additional claims have also been added to define the outer chamber as an autoclave which provides an elevated temperature and pressure. Dutton also fails to teach an apparatus wherein the outer chamber is an autoclave as claimed.

With regard to new claim 31, as noted above the claim recites an apparatus including the limitations of claims 5 and 6 as well as further clarifying the structure of the longitudinally extending shaft within the porous chamber. As such, the claim recites an apparatus comprising "a porous chamber within the outer chamber for containing a substance for dissolution or

Foster et al.

Application No.: 10/552,390

Filed: May 30, 2006

Page 11

suspension with the solvent, the porous chamber comprising a wall allowing passage of solvent and the substance dissolved or suspended in the solvent, and a longitudinally extending shaft in fluid communication with the inlet, wherein the shaft is porous along the length of the shaft". Thus, the claim defines a shaft that includes multiple holes along the length of the shaft. Dutton fails to disclose an apparatus having a shaft that is porous along its length. As noted in the Office Action (page 8, last paragraph), Dutton discloses a shaft having an opening at the end of the shaft, as opposed to a shaft that is porous along the length of the shaft as claimed.

PATENT

Atty Docket No.: MAP1130

Applicants submit that Dutton fails to anticipate the claimed invention as the reference fails to teach the each and every element of the claims. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejections under 35 U.S.C. §103

Applicants respectfully traverse the rejection of claims 10-12 under 35 U.S.C. §103 as allegedly being obvious in view of U.S. Patent No. 6,540,914 (Smith).

The Office Action alleges that Smith discloses an apparatus as recited in claim 1. Further the Office Action alleges that Smith teaches the claim limitations of claims 10-12, but acknowledges that the limitations of claims 10-12 are disclosed in a separate and distinct embodiment as compared to the apparatus allegedly disclosing the apparatus of claim 1. Regardless, the Action appears to allege that it would have been obvious to one skilled in the art to look at the embodiment of claim 1 and combine the limitations of claims 10-12 in view of the second embodiment of Smith.

As discussed above, without acquiescing to the reasoning presented in the Office Action, and to expedite prosecution of the instant application, Applicants have amended the claims to recite an apparatus having an "outer chamber for containing a dense gas, wherein the outer chamber is a pressure vessel". Smith fails to teach an apparatus wherein the outer chamber is a pressure vessel as recited in the amended claims and therefore fails to render the claims obvious. Additionally, with regard to claim 10, Applicants have amended the claim to recite that the

Foster et al.

Application No.: 10/552,390

Filed: May 30, 2006

element 62).

Page 12

baffles extend from the inner surface of the outer chamber. Smith fails to teach such a limitation since the baffles of the Smith apparatus extend from the inner chamber surface (Figure 2,

PATENT

Atty Docket No.: MAP1130

Applicants assert that the apparatus of Smith functions in general opposition to the claimed apparatus. Applicants note that the claimed apparatus employs a pressure vessel to provide elevated pressure to a substance within an inner porous chamber to facilitate dissolution or suspension of the substance into a dense gas solvent and movement of the solvent/substance solution from the inner porous chamber to the outer chamber through an outlet. Smith, on the other hand, generally discloses an oil filter device in which a fluid solution (e.g., oil and contaminants) enters an outer chamber and passes through an inner porous chamber to an outlet. the inner porous chamber being a filter to remove substance from the solution as the solution passes to the outlet. Thus the Smith device operates generally opposite to the claimed apparatus. Therefore, contrary to the assertions of the Office Action, one of skill in the art would not be motivated to combine various elements allegedly disclosed in two separate and distinct embodiments of Smith to arrive at the claimed apparatus having the limitations recited in claims 10-12. This is specifically evident with regard to the limitation of claims 11 and 12 which recite a plug provided to hold the substance within the inner porous chamber against the base of the inner chamber. In contrast, valve plate 98 of the apparatus of Smith is not configured to "hold the substance against the base of the inner chamber" as recited in claims 11 and 12, but rather is in opposing tension to the fluid within the inner chamber.

It is axiomatic that one cannot simply use the Applicants' disclosure as a "blueprint" to reconstruct, by hindsight, Applicants' claim (see, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 227 U.S.P.Q. 543 (Fed. Cir. 1985)). As the combined teachings do not teach all of the elements of the present claims, nor is there provided the motivation to combine, no prima facie case of obviousness has been established. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Foster et al.

Application No.: 10/552,390

Filed: May 30, 2006

Page 13

Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

Please charge Deposit Account No. 07-1896 in the amount of \$555.00 to cover a Petition for Three Month Extension of Time. Applicants believe that no additional fee is deemed necessary with the filing of this paper. However, the Commissioner is authorized to charge any fees deemed necessary with the filing of this paper, or credit any overpayments, to Deposit Account No. 07-1896 referencing the above-identified docket number.

Respectfully submitted,

PATENT

Atty Docket No.: MAP1130

Date: __January 25, 2010

Registration No.: 53,021 Telephone: (858) 638-6638

Facsimile: (858) 677-1465

DLA Piper LLP (US) 4365 Executive Drive, Suite 1100 San Diego, California 92121-2133 USPTO Customer No.: 28213